



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,273	09/26/2005	Gopalan Balasubramanian	04654/0200039-US0	8530
7278	7590	08/21/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,273	<b>Applicant(s)</b> BALASUBRAMANIAN ET AL.	
	<b>Examiner</b> Yong Chu	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21, 60-63, and 65-95 is/are pending in the application.
- 4a) Of the above claim(s) 60-63, 65-85 and 95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 86-89 is/are allowed.
- 6) ☒ Claim(s) 1-21 and 90-94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/20/05, 6/28/05, 3/17/06.</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

Claims 22-59 and 64 are cancelled by amendment filed on 26 September 2005. Claims 64 and 74-95 are added by amendment filed on 26 September 2005. Claims 1, 2, 7-9, 16-18, 20, 60-63, 65, 66, and 68-73 are amended by amendment filed on 26 September 2005. Therefore, claims 1-21, 60-63, and 65-95 are currently pending in the instant application.

### ***Information Disclosure Statement***

Applicant's Information Disclosure Statements, filed on 20 April 2005, 28 June 2005 and 17 March 2006 have been considered. Please refer to Applicant's copies of the PTO-1449 submitted herewith.

### ***Priority***

This application is a 371 of PCT/IB03/04442 filed on 8 October 2003, and claims the benefit of India Provisional Patent Application 922/MUM/2002, filed on 23 October 2002.

### ***Response to Lack of Unity***

The response to the restriction request with provisionally election of Group I (claims 1-21, 60-63 and 65-94 (in part), wherein Y is  $-\text{C}(\text{O})\text{NR}_4$ , X is O or  $\text{S}(\text{O})_m$  and the remaining substituents are as depicted in claim 1) *with traverse* by Applicants' representative, Jay P. Lessler dated on 30 June 2006, has been considered.

The traversal is on the ground(s) that the structural components of the compounds in Group I are the same as that in Group V, with the exception of X, which is  $-\text{NR}_5$  in

Art Unit: 1626

Group V, and O or S(O)m in Group I. This is not found persuasive because the core structures of the compounds in Group I and Group V are different as stated in the Remark. The core structure of the compounds in Group I is a dibenzo[b,d]furan group, and the core structure of the compounds in Group V is a carbazole group. In addition, Groups I and V lack a special technical feature because they fail to define a contribution over O'Brien (WO 98/09934), and Shen (U.S. Patent 3,759,948), because both the prior arts disclose dibenzo[b,d]furan as a special technical feature. Therefore, the requirement is still deemed proper.

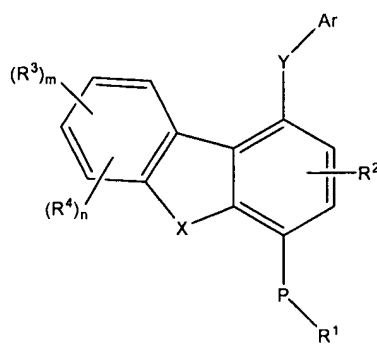
### ***Status of the Claims***

During a telephone conversation with Applicants' representative, Attorney Jay P. Lessler dated on 17 August 2006, Applicants agree to withdraw the method claims 60-63, and 65-85 from Group I. Rejoin of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable, if the process claims satisfy the requirements of 35 U.S.C §112 first and second paragraph.

Claims 1-21, 60-63 and 65-94 (in part) and 95 are further withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



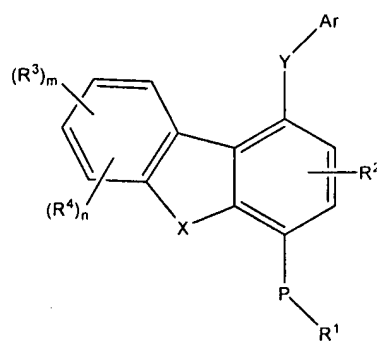
Compounds of Formula (I) , wherein:

**X** is oxygen or S(O)<sub>m</sub>, wherein **m** is 0, 1, or 2;

**Y** is -C(O)NR<sup>4</sup>, wherein **R**<sup>4</sup> is defined in claim 1; and the remaining substituents are defined in claim 1; or its analog, tautomer, regioisomer, stereoisomer, enantiomer, diastereomer, polymorph, pharmaceutically acceptable salt, N-oxide, or pharmaceutically acceptable solvate thereof.

Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter is as follows:



Compounds of Formula (I) , wherein:

**X** is NR<sup>5</sup>, wherein **R**<sup>5</sup> is defined in claim 1;

Art Unit: 1626

Y is  $-\text{NR}^4\text{SO}_2$ ,  $-\text{SO}_2\text{NR}^4$  or  $-\text{NR}^4\text{C}(\text{O})$ , wherein  $\text{R}^4$  is defined in claim 1; and the remaining substituents are defined in claim 1; or its analog, tautomer, regioisomer, stereoisomer, enantiomer, diastereomer, polymorph, pharmaceutically acceptable salt, N-oxide, or pharmaceutically acceptable solvate thereof.

As a result of the election and the corresponding scope of the invention identified supra, claims 1-21, 60-63 and 65-94 (in part) are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups which are chemically recognized to differ in structure, function, and reactivity.

Claims 1-21, and 86-94 are ready for examination.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21, and 90-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1-21, and 90-94 are rejected due to claiming polymorph of a compound of Formula (I). By definition, polymorph is a specific crystalline form of a compound that can crystallize in different forms. The specification does not reasonably

Art Unit: 1626

provide enablement for forming crystalline of each of the compound list in the claims. It is well known to one skilled in the art that not all compounds can form crystalline.

Because of high level of unpredictability associated with crystalline of the compounds, a greater amount of evidentiary support is needed to fully satisfy the requirement of 35 U.S.C 112, first paragraph. It is noted that crystallization art is unpredictable, requiring each embodiment to be individually assessed for the possibility.

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that compounds fall within the scope of a claim will possess the crystalline form of the compound. To practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which compounds would form crystalline, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The definition of  $R^1$  is defined by  $-C(O)-R^1$ ,  $-S(O)m-R^1$ , ..., which is indefinite.

### ***Conclusion***

Claims 86-89 are allowed.

Claims 1-21, and 90-94 are rejected.

Art Unit: 1626


***Telephone Inquiry***

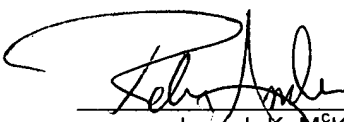
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759.

The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
\_\_\_\_\_  
Yong Chu, Ph.D.  
Patent Examiner  
Art Unit 1626

  
\_\_\_\_\_  
Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626